



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/674,280

09/29/2003

Richard A. Schomburg

117163. 00091

3122

21324

7590

11/14/2006

HAHN LOESER & PARKS, LLP

One GOJO Plaza

Suite 300

AKRON, OH 44311-1076

EXAMINER

CHANG, SUNRAY

ART UNIT

PAPER NUMBER

2121

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,280

Applicant(s)

SCHOMBURG, RICHARD A.

Examiner

Sunray Chang

Art Unit

2121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in responsive to the paper filed on October 7th, 2006.

Claims 1 – 15 are presented for examination.

Claims 1 – 15 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1 – 8 and 10 – 15 are rejected** under 35 U.S.C. 102(e) as being anticipated by Esteller et al. (U.S. Patent No. 6,594,524, and referred to as **Esteller** hereinafter).

Regarding independent claim 1, Esteller teaches,

An apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10), said apparatus comprising:

a probabilistic neural network (see Brief Description of Drawing Figure 32) which is adapted to receive a set of values representing the physiological signal and which contains a

Art Unit: 2121

number of event classes which represent physiological events and which are respectively determined by a number of comparative values (see col. 9, lines 48-52), which network is adapted on the basis of the comparison of the set of values with the comparative values to implement an association of the physiological signal represented by the set of values with one of the event classes (see col. 36, lines 51-67 and also see col. 37, lines 1-36)

an updating unit connected to the probabilistic neural network for updating the comparative values of an event class on the basis of the set of values of at least one physiological signal which has been associated with said event class in a preceding association operation. [FIG. 2 illustrates the scheme of the multi-level control, ... The main goal of the multi-level control is to keep the patient from having seizures despite environmental and physiological load disturbances. ... a supervisory control is implemented providing (a) continuous regulation of the controlled variables, (b) adaptation to external or internal changes over time, and (c) a knowledge base used to accomplish the regulation and adaptation by incorporating information as it arises, and updating the system settings and parameters appropriately. [Col. 6, lines 8 – 20; Fig. 2]

Regarding dependent claim 2, Esteller teaches, the apparatus of claim 1, wherein:

the updating unit is so designed that upon updating of the comparative values an average value is formed from a number of value sets which have previously resulted in an association of the physiological signals which they represent with the event class to be updated and wherein the updating operation is effected on the basis of the average value formed in that way. (see col. 21, Average Power or Moving Average Power)

Regarding dependent claim 3, Esteller teaches, the apparatus of claim 1 wherein:

the updating unit is so designed that upon updating of the comparative values exponential weighting of a number of value sets which have previously resulted in an association of the physiological signals which they represent with the event class to be updated is effected and wherein the updating operation is effected on the basis of the exponentially weighted value sets. (see col. 23, Average Nonlinear Energy or Moving Average Nonlinear Energy, more specifically col. 24, lines 3-26)

Regarding dependent claim 4, Esteller teaches, the apparatus of claim 3 wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Thresholded Nonlinear Energy, lines 27-47)

Regarding dependent claim 5, Esteller teaches, the apparatus of claim 4 wherein:

different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 6, Esteller teaches, the apparatus of claim 5, further

comprising:

a signal input for the input of a physiological signal; (see Abstract, lines 4-10) and

Art Unit: 2121

a transformation unit (see Figure 3, element 200) which is connected to the signal input for receiving the physiological signal and which is adapted to implement a transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation operation; (see col. 18, lines 41-60 and also see col. 20, lines 26-36) wherein

the probabilistic neural network is connected to the transformation unit for receiving the values as the value set. (see Figure 1, element 200)

Regarding dependent claim 7, Esteller teaches, the apparatus of claim 6, wherein:

the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets. (see col. 28, lines 21-44)

Regarding independent claim 8, Esteller teaches,

An implantable medical device (see col. 3, lines 4-7), comprising:

an apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10) comprising:

a probabilistic neural network (see Brief Description of Drawing Figure 32) which is adapted to receive a set of values representing the physiological signal and which contains a number of event classes which represent physiological events and which are respectively determined by a number of comparative values (see col. 9, lines 48-52), which network is adapted on the basis of the comparison of the set of values with the comparative values to

Art Unit: 2121

implement an association of the physiological signal represented by the set of values with one of the event classes (see col. 36, lines 51-67 and also see col. 37 lines 1-36)

an updating unit connected to the probabilistic neural network for updating the comparative values of an event class on the basis of the set of values of at least one physiological signal which has been associated with said event class in a preceding association operation. [FIG. 2 illustrates the scheme of the multi-level control, ... The main goal of the multi-level control is to keep the patient from having seizures despite environmental and physiological load disturbances. ... a supervisory control is implemented providing (a) continuous regulation of the controlled variables, (b) adaptation to external or internal changes over time, and (c) a knowledge base used to accomplish the regulation and adaptation by incorporating information as it arises, and updating the system settings and parameters appropriately. [Col. 6, lines 8 – 20; Fig. 2]

Regarding dependent claim 10, Esteller teaches, the apparatus of claim 1, wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Thresholded Nonlinear Energy, lines 27-47)

Regarding Claim 11, Esteller discloses:

Regarding dependent claim 11, Esteller teaches, the apparatus of claim 2, wherein:

the updating unit is so designed that updating of an event class is effected after the association of a n-th value set with said event class, wherein that defines a predetermined number of value sets. (see col. 24, Duration of Thresholded Nonlinear Energy, lines 27-47)

Regarding dependent claim 12, Esteller teaches, the apparatus of claim 10, wherein:
different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 13, Esteller teaches, the apparatus of claim 11, wherein:
different values for n are to be associated with different event classes. (see col. 31, Window Length Selection, lines 52-56)

Regarding dependent claim 14, Esteller teaches, the apparatus of claim 1, further comprising:
a signal input for the input of a physiological signal (see Abstract, lines 4-10); and
a transformation unit (see Figure 3, element 200) which is connected to the signal input for receiving the physiological signal and which is adapted to implement a transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation operation (see col. 18, lines 41-60 and also see col. 20, lines 26-36); wherein the probabilistic neural network is connected to the transformation unit for receiving the values as the value set. (see Figure 1, element 200)

Regarding dependent claim 15, Esteller teaches, the apparatus of claim 14, wherein:
the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets. (see col. 28, lines 21-44)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. **Claim 9 is rejected** under 35 U.S.C. 103(a) as being unpatentable over **Esteller**, and in view of Gray et al. (U.S. Patent No. **6,144,879** and referred to as **Gray** hereinafter).
- (**Esteller** as set forth above generally discloses the basic inventions.)

Regarding dependent claim 9,

Esteller teaches an apparatus for the classification of physiological events on the basis of physiological signals (see Abstract, lines 4-10) as cited above.

Gray teaches a medical device is in the form of a cardiac pacemaker or defibrillator [Abstract, Fig. 4, and Fig. 8], for the purpose of constituting a pulse generator [Col. 1, lines 23 – 26].

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of **Esteller** to include "a medical device is in the form of a cardiac pacemaker or defibrillator", for the purpose of constituting a pulse generator [Col. 1, lines 23 – 26].

Response to Amendment

Claim Rejections - 35 USC § 102 & 103

4. Applicants cite the examiners' citation regarding "**Esteller** fails to disclose an updating unit" which citation has been reconsidered and has been withdrawn in current office action.

Esteller does teach an updating unit by expressly indicating the external PC used for updating the system settings and parameters as disclosed above.

5. The forth 103 rejections to claims 1 and 8 have been withdrawn.

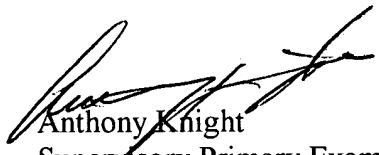
Art Unit: 2121

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sunray Chang who may be reached Monday through Friday, between 8:00 a.m. and 5:00 p.m. EST. via telephone number (571) 272-3682 or facsimile transmission (571) 273-3682 or email sunray.chang@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight can be reached on (571) 272-3687.

The official facsimile transmission number for the organization where this application or proceeding is assigned is (571) 273-8300.



Anthony Knight
Supervisory Primary Examiner
Group Art Unit 2121
Technology Center 2100
U.S. Patent and Trademark Office

November 9, 2006